



MAR 26 2008

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,968,976

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,968,976, which claims the human drug product FOSRENOL® (lanthanum carbonate hydrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 951 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 951 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 22, 2007 (72 Fed. Reg. 28700), would be 1,373 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,538 - 614) + 911 \\ &= 1,373 \text{ days (3.8 years)}\end{aligned}$$

Since the regulatory review period began February 13, 1998, before the patent issued (October 19, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From February 13, 1998, to and including October 19, 1999, is 614 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,373 days, would extend the patent from March 19, 2016, to December 22, 2019, which is beyond the 14-year limit (the approval date is October 26, 2004, thus the 14 year limit is October 26, 2018). The period of extension is thus limited to October 26, 2018, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the

term of the patent from its original expiration date, March 19, 2016, to and including October 26, 2018, or 951 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,968,976
Granted:	October 19, 1999
Original Expiration Date ¹ :	March 19, 2016
Applicant:	Barry A. Murrer, <i>et al.</i>
Owner of Record:	Shire International Licensing B.V.
Title:	Pharmaceutical Composition Containing Selected Lanthanum Carbonate Hydrates
Product Trade Name:	FOSRENOL® (lanthanum carbonate hydrate)
Term Extended:	951 days
Expiration Date of Extension:	October 26, 2018

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy RE: FOSRENOL® (lanthanum
Food and Drug Administration carbonate hydrate)
10903 New Hampshire Ave., Bldg. 51, Rm. 6222 FDA Docket No.: 2005E-0248
Silver Spring, MD 20993-0002

Attention: Beverly Friedman